Supreme Court, U.S.
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No. 93-425

In The

Supreme Court of the United States

October Term, 1993

MUTUAL OF OMAHA LIFE INSURANCE COMPANY,

Petitioner,

v.

MARY P. DAHL-EIMERS,

Respondent.

Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

PETITIONER'S SUPPLEMENTAL BRIEF

THOMAS E. JOHNSON
STEVEN D. DAVIDSON
of BAIRD, HOLM, MCEACHEN, PEDERSEN, HAMANN & STRASHEIM
1500 Woodmen Tower
Omaha, Nebraska 68102-2068
(402) 344-0500

Counsel of Record for Petitioner

RALPH A. PETERSON
of BEGGS & LANE
3 West Garden Street
Post Office Box 12950
Pensacola, Florida 32576-2950
(904) 432-2451

Counsel for Petitioner

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

This supplemental brief is submitted for the purpose of bringing to the Court's attention the order of the district court rendered in this case on September 21, 1993, granting Mutual's Motion to Dismiss. The order is currently unreported, but is appended to this brief.

As noted in footnote 5 of Mutual's Petition for a Writ of Certiorari, Plaintiff's claims seeking declaratory relief, permanent injunctive relief, and damages remained pending and active in the district court during the appeal of the district court's order denying Plaintiff's Motion for a Preliminary Injunction. Upon learning of the changed circumstances discussed in the Petition for a Writ of Certiorari, Mutual filed a Motion to Dismiss in the district court, arguing that Plaintiff's claim for a declaratory judgment was no longer ripe for decision, and that her claims for a permanent injunction and for damages were moot.

In the order entered September 21, 1993, the district court agreed and granted the Motion to Dismiss. In the order, Judge Vinson explained that the numerous uncertainties and contingencies surrounding Plaintiff's physical condition and the medical procedures which may one day be appropriate for her, preclude a meaningful analysis of the pertinent issues and render the claim for declaratory relief no longer ripe. The district court also held that the change of circumstances eliminates any need to enjoin Mutual from denying a request for preauthorization of benefits for Plaintiff's participation in the Moffitt clinical trial of HDC-ABMT, and that Plaintiff's request for injunctive relief has therefore become moot. Finally, the district court found the exception to the mootness doctrine for cases capable of repetition yet

evading review inapplicable to these facts, and concluded that Plaintiff's request for damages and attorney fees is insufficient to create a justiciable controversy.

Judge Vinson's order demonstrates the clear error in the Eleventh Circuit's assertion of jurisdiction over this moot controversy. It correctly analyzes issues of justiciability closely related to those raised in the Petition for a Writ of Certiorari. Mutual respectfully requests that it be given substantial weight in the Court's consideration of the Petition.

Respectfully submitted,

MUTUAL OF OMAHA LIFE INSURANCE COMPANY,
Petitioner

/s/ THOMAS E. JOHNSON
STEVEN D. DAVIDSON
of BAIRD, HOLM, MCEACHEN, PEDERSEN, HAMANN & STRASHEIM
1500 Woodmen Tower
Omaha, Nebraska 68102-2068
(402) 344-0500

Counsel of Record for Petitioner

RALPH A. PETERSON
of BEGGS & LANE
Post Office Box 12950
Pensacola, Florida 32576-2950
(904) 432-2451

Counsel for Petitioner

October, 1993.

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IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

MARY P. DAHL-EIMERS,

Plaintiff,

v.

MUTUAL OF OMAHA LIFE INSURANCE COMPANY,

Defendant.

Case No. 92-30254-RV

(Filed Sept. 21, 1993)

ORDER

Pending is defendant's motion to dismiss. (Doc. 67). For the reasons set forth herein, the relief requested is GRANTED.

I. BACKGROUND

Most of the background facts in this matter are set out in my Order and Memorandum Opinion of July 29, 1992. The plaintiff, Mary P. Dahl-Eimers, suffers from Stage IV metastatic breast cancer. At the time this lawsuit was filed, in July 1992, Dahl-Eimers sought to undergo a procedure identified generally as high dose chemotherapy with autologous bone marrow transplant ("HDC-ABMT"). Dahl-Eimers' cancer apparently was in remission at that time, but her treating physicians had advised her that she should immediately undergo HDC-ABMT.

Dahl-Eimers sought to enter a clinical trial of HDC-ABMT which was underway at the H. Lee Moffitt Cancer Center and Research Institute, Inc., at the University of

South Florida ("Moffitt"), located in Tampa, Florida. That clinical trial utilized three chemotherapy drugs known as Ifosfomide, Carboplatinum, and Etoposide ("I.C.E."). I will refer to this HDC-ABMT clinical trial as the "Moffitt I.C.E. trial."

Dahl-Eimers was at that time, and still is, insured under a major medical expense policy issued by the defendant, Mutual of Omaha Life Insurance Company ("Mutual").[1] This policy required Mutual to reimburse Dahl-Eimers for the cost of "medically necessary" services or supplies. The policy defines "medically necessary" as follows:

> A "Medically Necessary" service or supply means one which: (a) is appropriate and consistent with a diagnosis in accord with accepted standards of community practice; (b) is not considered experimental, and (c) could not have been omitted without adversely affecting the insured person's condition or the quality of medical care.

Under this definition, a service or supply which is "considered experimental" would not qualify as "medically necessary," and would not, therefore, be covered by the policy.

In May or early June 1992, Moffitt submitted to Mutual a request for preauthorization of benefits for Dahl-Eimers to participate in the Moffitt I.C.E. trial. On June 10, 1992, Mutual denied the request, concluding that

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[1] Because this insurance policy is not an employment benefit, the provisions of the Employee Retirement Income Security Act [29 U.S.C. §§ 1001 *et seq.*] do not apply.

the proposed treatment was not "medically necessary" within the meaning of the policy. In response to Mutual's denial of benefits, Dahl-Eimers filed this lawsuit. Dahl-Eimers sought an injunction directing Mutual to discontinue its refusal to preauthorize benefits for the Moffitt I.C.E. trial, declaratory judgment that the procedure was not experimental, and damages.

Simultaneously, Dahl-Eimers filed a motion for a preliminary injunction. Dahl-Eimers alleged that she desired immediately to begin the Moffitt I.C.E. trial and that grave medical consequences would result from any delay. I gave expedited review to the request for a preliminary injunction; a hearing was held on July 20-21, 1992, eighteen days after the complaint was filed. At the close of evidence and argument, I ruled from the bench and denied the request for preliminary injunction. By my Order and Memorandum Opinion of July 29, 1992, I explained my finding that Dahl-Eimers had failed to demonstrate a substantial likelihood of success on the merits of her claim. I recognized that "experimental" may be ambiguous in certain contexts, but concluded that the policy term "experimental" was not ambiguous when applied to the "actual procedure being contemplated by the plaintiff for her treatment." Within the facts of this case, the inescapable conclusion was that the Moffitt I.C.E. trial was experimental. That factual finding was the core of my decision.

At the request of the plaintiff, and believing that my ruling involved a controlling question as to which there was a substantial ground for difference of opinion and that an immediate appeal might materially advance the litigation, I certified the order for interlocutory appeal.

See 28 U.S.C. § 1292(b) (1988). I also indicated that time was of the essence. The United States Court of Appeals for the Eleventh Circuit granted Dahl-Eimers' motion for an interlocutory appeal. By opinion issued March 9, 1993, the Eleventh Circuit vacated and remanded.

The Eleventh Circuit held that "the phrase 'considered experimental,' standing alone in a major medical insurance policy, is ambiguous as a matter of law." *Dahl-Eimers v. Mutual of Omaha Life Ins. Co.*, 986 F.2d 1379, 1380 (11th Cir. 1993). According to the Eleventh Circuit, the phrase is ambiguous because some reasonable interpretations of it may result in coverage for HDC-ABMT while others may not. *Id.* at 1382. The Eleventh Circuit did not discuss whether any reasonable interpretation of the phrase "considered experimental" could result in coverage for the specific treatment which was at issue in this case – the Moffitt I.C.E. trial. Nor did it address the fact-controlled findings inherent in the case. Instead, the Eleventh Circuit focused on general HDC-ABMT, without regard to the particular course of treatment which is the subject of the coverage dispute between Dahl-Eimers and Mutual.

The Eleventh Circuit issued its opinion in March 1993; however, no mandate followed until August 10, 1993. In the meantime, on April 23, 1993, Dahl-Eimers withdrew her motion for preliminary injunction. Dahl-Eimers filed an amended complaint on May 11, 1993. (Doc. 66). Mutual now has moved to dismiss the amended complaint for lack of subject matter jurisdiction, pursuant to rule 12(b)(1) and 12(h)(3), Federal Rules of

Civil Procedure. Mutual argues that changed circumstances have rendered non-ripe the claim for declaratory judgment and mooted the request for an injunction.

II. DISCUSSION

Under Article III of the U.S. Constitution, federal courts may adjudicate only actual, ongoing cases or controversies. *Lewis v. Continental Bank Corp.*, 494 U.S. 472, 477, 110 S.Ct. 1249, 108 L.Ed.2d 400, 410 (1990). Federal courts are not empowered to issue advisory opinions, to answer hypothetical questions, or to resolve disputes that are not yet ripe or that have, through the passage of time and changed circumstances, become moot. This court has jurisdiction over Dahl-Eimers' claim only if it presents a live, ongoing case or controversy.

A. Ripeness of Declaratory Judgment Claim

The Declaratory Judgment Act, Title 28, United States Code, Section 2201(a), grants federal courts jurisdiction to issue declaratory judgments only in cases of "actual controversy." A threshold question in any declaratory judgment action is whether a justiciable controversy exists. *United States Fire Ins. Co. v. Caulkins Indiantown Citrus Co.*, 931 F.2d 744, 747 (11th Cir. 1991).

The two most oft-cited statements of the ripeness rule have been handed down by the Supreme Court of the United States. In *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273, 61 S.Ct. 510, 512, 85 L.Ed. 826 (1941), the Court stated:

> "The difference between an abstract question and a 'controversy' contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy. Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

More recently, the Court explained that "the question of ripeness turns on 'the fitness of the issues for judicial decision' and 'the hardship to the parties of withholding court consideration.' " *Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 200-01, 103 S.Ct. 1713, 1720, 75 L.Ed.2d 752 (1983) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149, 87 S.Ct. 1507, 1515, 18 L.Ed.2d 681, 691 (1967). As is clear from these and other opinions on the subject, the ripeness test is pliable and above all, is fact-driven.

The undisputed facts as they now exist in this matter lead me to conclude that the controversy between Dahl-Eimers and Mutual is not of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. *See Maryland Cas. Co., supra.* It is undisputed that Dahl-Eimers is currently in complete remission, and has no present plan to undergo HDC-ABMT via the Moffitt I.C.E. trial, or otherwise. Dahl-Eimers testified as follows in her April 23, 1993, deposition:

> Q (By counsel for Mutual). Let me ask you this: As we sit here today, is it your intent to not

go forward with the bone marrow transplant until such time as you have experienced some recurrence of your disease?

A (By Dahl-Eimers). Yes.

Q. Is that based upon the advice and consultation of any physician?

A. Yes.

Q. Can you tell me each physician knowledgeable about your medical condition who you believe would state that that is their advice and opinion?

A. Dr. Vaughan.

Q. Okay.

A. Dr. Chang, Dr. Contraris.

Q. Okay, can you think of any others? I mean, if I wanted to go out and ask each doctor who has advised you of that or rendered advice through other people to you –

A. No, I think we have limited it to the people that know my condition. I think that those are the main doctors.

Q. Okay. Have any doctors communicated to you, directly or indirectly, the opinion that if you are going to have a bone marrow transplant, you should not wait for a recurrence but rather go forward immediately?

A. No.

(Dahl-Eimers Dep. at 33-34).

Thus, Dahl-Eimers no longer presently seeks to undergo HDC-ABMT. Rather, she has decided, based on

the advice of her physicians, to wait until a recurrence of symptoms, and then determine if HDC-ABMT is an appropriate treatment. Only when her symptoms recur will Dahl-Eimers and her physicians be able to assess her treatment options, one of which might be some form of HDC-ABMT:

> Q (By counsel for Mutual). And if all things continue in the status quo today, that is no further pain or other symptoms, no increase in your blood markers, do you intend to undergo any form of therapy?
>
> A (By Dahl-Eimers). Form of therapy?
>
> Q. Right, any radiotherapy, any chemical therapy, any dietary therapy in addition to what you are already doing; or do you intend to just continue the way you are right now?
>
> A. Until something recurs?
>
> Q. Is that your intent?
>
> A. Yeah.
>
> Q. What is your intent if you should experience a reoccurrence of symptoms of your disease?
>
> A. What is my plan of action?
>
> Q. Intent with regard to therapy or your plan of action, that's a good term.
>
> A. It depends on what the diagnosis is.
>
> Q. I take it that if such an event occurs you will go see Dr. Chang?
>
> A. Yes.

Q. And you will consult with him about a course of action?

A. Yes.

Q. And your understanding would be that that course of action would be dependent upon what those symptoms were and what –

A. Right, right.

Q. – was the nature of your disease?

A. Exactly.

Q. As you sit here today do you consider one of the possibilities at that point in time to be a bone marrow transplant?

A. Yes.

(Dahl-Eimers Dep. at 41-43).

Moreover, Dahl-Eimers is now considering numerous alternative HDC-ABMT procedures, offered at hospitals nationwide, in the event that she and her physicians decide at a later date that she should undergo HDC-ABMT. In addition to the Moffitt I.C.E. trial, Dahl-Eimers has explored, and is continuing to explore, HDC-ABMT trials at the University of Alabama at Birmingham, Memorial Sloan-Kettering Hospital, the Dana Farber Cancer Institute, the Fred Hutchinson Center Research Center, and the M. D. Anderson Cancer Center of the University of Texas, among others. At this point, Dahl-Eimers and her physicians have not decided which of these, or other, HDC-ABMT trials might be appropriate for her in the future.

As is clear from Dahl-Eimers' testimony, there are too many contingencies and uncertainties for a meaningful

resolution of her claim for declaratory judgment. I realize that Dahl-Eimers' physicians feel that there is a high probability that her cancer will return. Yet, it is impossible for them to predict when that might occur, nor is it anything like a certainty. She has already received state-of-the-art treatment, which has apparently been effective in placing the cancer into remission. It may be that many years will pass before Dahl-Eimers experiences, if ever, a change in her condition significant enough to merit HDC-ABMT treatment.

More to the point, however, it is impossible to predict changes in Dahl-Eimers' medical condition between now and the time she and her physicians might eventually consider HDC-ABMT. Dahl-Eimers' condition may be such that HDC-ABMT is not appropriate; some less drastic treatment may be preferable or her condition might render her ineligible for HDC-ABMT. The nature of Dahl-Eimers' medical condition at the time in which she desires to undergo HDC-ABMT is crucial to a determination of whether that treatment might be medically necessary. At this point, one can only speculate as to what her condition might be at that time.

Equally uncertain is which of the many variations of HDC-ABMT Dahl-Eimers might desire to undergo. At the present, Dahl-Eimers is considering alternative HDC-ABMT procedures at numerous research hospitals. Each hospital has its own specific approach to HDC-ABMT, and the approaches vary in significant respects. Different drugs, dosages, and schedules are used from procedure to procedure, and the different procedures have different eligibility criteria. Also, the procedures evolve over time, so that it is impossible to predict today what specific

procedures will be offered at a date in the future when Dahl-Eimers might seek to undergo HDC-ABMT, and whether they will be "experimental" at that time.

Nor is it possible to predict what will be the state of medical and scientific knowledge at some unknown date when Dahl-Eimers might seek to undergo HDC ABMT. Medical knowledge about the efficacy of treating breast cancer with a particular regimen of HDC-ABMT lies at the heart of this coverage dispute. The medical research community is actively trying to accumulate such knowledge. The result of that effort would be dispositive of the issue of whether a particular regimen would be "considered experimental" for a particular patient at a particular time. It may well be that, at the point in time when Dahl-Eimers desires to undergo HDC-ABMT – if that point is ever reached – enough will be known about the efficacy of the treatment to obviate a coverage dispute.

Dahl-Eimers seeks to avoid these uncertainties by requesting a broad declaratory judgment that HDC-ABMT is not experimental. However, the important point that seems to be regularly overlooked is that HDC-ABMT is not a single, uniform procedure. The chemotherapy drugs to be utilized must be independently evaluated. Some trials of a particular drug combination of HDC-ABMT – Phase I for instance – would probably be "considered experimental" for any patient. Other trials – a Phase II or Phase III – might more readily be considered non-experimental. Some clinical trials consist of combinations of drugs and dosages which have never been tried on human subjects. Other trials may be refinements of earlier versions which have yielded favorable results, such as tumor shrinkage and long-term survival. As

should be apparent, it is misleading to phrase the issue in terms of whether *HDC-ABMT* is considered experimental. Perhaps a cancer research faculty or a convention of oncologists could make such a declaration as to a specific drug procedure, but a court is ill-disposed, and would be ill-advised, to try. Rather, the appropriate inquiry for a court should be whether a particular treatment which a particular patient desires is "considered experimental." That question is not ripe for resolution in this matter.

Any attempt to issue a declaratory judgment in this matter, at this point, would force me to render an opinion advising what the law might be upon a hypothetical state of facts. *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-42, 57 S.Ct. 461, 463-64, 81 L.Ed. 617 (1937). Of course, the presence of a contingency will not always render declaratory judgment actions non-justiciable. *See Browning-Ferris Indus. of Alabama, Inc., v. Alabama Dep't of Envtl. Mgt.*, 799 F.2d 1473 (11th Cir. 1986). In this case, however, the contingencies and variables are so substantial that they preclude a meaningful analysis of the pertinent issues. Thus, I conclude that the request for declaratory judgment is not ripe.

B. Mootness of Request for Injunction

Likewise, I conclude that the request for injunctive relief has become moot. Dahl-Eimers' testimony shows that she no longer has the present desire to begin the Moffitt I.C.E. trial or any other particular HDC-ABMT trial. Instead, Dahl-Eimers will await a change in her medical condition before she reconsiders HDC-ABMT. The time at which she stood ready to undergo HDC-

ABMT has passed. Thus, there is no longer a need to enjoin Mutual from denying a preauthorization of benefits for her to participate in an HDC-ABMT trial.

Nor does this matter fall within the exception to the mootness doctrine for cases that are capable of repetition, but evading review. In order for a challenged action to fit within this exception, two requirements must be met. *See Lewis v. Continental Bank*, 494 U.S. 472, 481, 110 S.Ct. 1249, 108 L.Ed.2d 400, 412 (1990). First, the injury must be of a type that is likely to happen to the plaintiff again. That is, there must be a "reasonable expectation that the same complaining party would be subjected to the same action again." *Weinstein v. Bradford*, 423 U.S. 147, 149, 96 S.Ct. 347, 46 L.Ed.2d 350, 353 (1975). Second, the complained-of action must inherently be of such a limited duration that it is likely to always become moot before it can be litigated. *Id.; Lewis v. Continental Bank Corp., supra.*

Neither of these requirements is satisfied in this case. First, it cannot be said with any degree of certainty that Dahl-Eimers will be subjected to the same action again. As I have discussed at length above, there are too many contingencies and unknown variables about what the future may hold for this dispute. Second, the injury here complained of is not of such an inherently limited duration that it is likely to always become moot before litigation is completed. There are numerous cases in which the issue of insurance coverage for HDC-ABMT has been decided before the controversy was mooted. These cases demonstrate that judicial resolution of this type of dispute is not precluded by the nature of the dispute. Rather,

as I have already done once in this case, expedited procedures are available to resolve this type of dispute while it is still a justiciable controversy.

Finally, Dahl-Eimers' claim is not saved from mootness by her request for damages. The amended complaint contains a prayer for relief for damages Dahl-Eimers has allegedly suffered, apparently as a result of Mutual's wrongful refusal to grant preauthorization for the Moffitt I.C.E. trial. Dahl-Eimers would only be entitled to damages if Mutual had indeed wrongfully denied coverage for the proposed treatment. As was clear from the evidence produced at the preliminary injunction stage, Mutual's refusal to preauthorize Dahl-Eimers for the Moffitt I.C.E. trial was not wrongful. I restate now what I found then: as a matter of fact, the Moffitt I.C.E. trial was not covered by Dahl-Eimers' insurance policy.

This is because, under no *reasonable* definition of the term "considered experimental" – even construing the term against Mutual – could the Moffitt I.C.E. trial be considered other than experimental. That the term may be ambiguous – as the Eleventh Circuit held it to be – does not mean that it is meaningless. The Moffitt I.C.E. trial employed a previously untested combination of chemotherapy drugs which the protocol document itself describes as a "novel multi-agent regimen." A major component of the Moffitt I.C.E. trial was Phase I research – an attempt to determine the maximum dosages of the chemotherapy drugs that can be tolerated by patients with a variety of cancers.

Clearly, this type of procedure is preliminary to determining whether the particular combination of drugs

may be appropriate for treating particular cancer. Those who run the trial – the "investigators" – do not know the tolerable, much less, the proper, dosage for individual patients. Plainly, the "investigators" are experimenting, on human subjects, in order to determine the tolerable dosage of I.C.E. which can then be tested to determine whether it has any discernible benefit for patients. Implied in this Phase I study is that a certain percentage of the participants will probably receive a dosage that will be beyond the point of maximum tolerance, i.e. fatal. To hold that such a procedure is other than "considered experimental" would erase any meaningful distinction between experimental and conventional medicine. Mutual's refusal to pay for Dahl-Eimers' participation in the Moffitt I.C.E. trial was not wrongful. Thus, no damages liability could flow from Mutual's denial of coverage.

Finally, although the parties have not addressed the issue, I note that Dahl-Eimers' request for attorney's fees does not save her claim from mootness. The Supreme Court recently has stated that an interest in attorney's fees is insufficient to create an Article III case or controversy where none exists on the merits of the underlying claim. *Lewis v. Continental Bank Corp., supra,* 494 U.S. at 480, 108 L.Ed.2d at 412.

III. CONCLUSION

For the reasons set forth above, I conclude that Dahl-Eimers' claim has been rendered non-justiciable by the changes in circumstances which have occurred since this suit was initiated. As a result, this court lacks jurisdiction

over the subject matter of her claim. Accordingly, Mutual's motion to dismiss is GRANTED.

DONE AND ORDERED this 21st day of September, 1993.

/s/ Roger Vinson
ROGER VINSON
United States
District Judge